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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,440	03/17/2000	Hiroki Nakae	HIRA.0003	3095

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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

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24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/527,440	NAKAE ET AL.
	Examiner	Art Unit
	Lori A. Clow, Ph.D.	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 May 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4 and 30-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-4 and 30-37 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

4) Interview Summary (PTO-413) Paper No(s) _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Applicants' arguments, filed 13 May 2003, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4 and 30-37 are currently pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,251,588 B1 (Shannon et al.) in view of US 6,007,231 (Vigj et al. (also WO/98/06872)), in further view of US 6,083,763 (Balch). *This is a new grounds of rejection.*

Shannon et al. disclose a method for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence. This includes the design of primers that have a high potential for hybridization (column 18, lines 59-62). The instant invention requires a primer design system that includes a means for selecting genomic DNA sequence from a database, a means for predicting exons in the sequence and storing them, and a means for using the predicted exons as templates to design a primer pair to the exon, and a means to collate the primer pairs. The primer pairs of the instant invention are selected based on parameters, such as melting temperature, GC content, and base length. Specificity of each primer is also evaluated.

Shannon et al. teach that their invention is a computer based method such that the input means may permit manual input of the target sequence or may also include an input means from a standard format file such as GenBank (column 39, lines 1-8). The system further comprises a means for controlling the computer to carry out the identification of a subset of oligonucleotide sequences within the number of unique oligonucleotide sequences based upon automated examination of the stored parameter values. The system also provides a means for the computer to carry out an identification of oligonucleotide sequences in the subset that are clustered along a region of the nucleotide sequence that is hybridizable to the target nucleotide sequence (column

39, lines 22-33). Finally the system is able to output the results (see Table 3 for example). The parameters used for selection of oligonucleotides include duplex melting temperature, which inherently implies analysis of GC content (see column 14, lines 35-67). The steps involve parsing sequences into sets of overlapping sequences and evaluating parameters that will predict the hybridization of the probe or primer (column 19, lines 13-23). While Shannon et al. do not specifically state that this method is useful for primer design based upon exon prediction as in the instant application, they do state, as above, that this is useful for a variety of primer/probe purposes, including locating regions of interest. At the time the invention was made, it was known in the art that exon prediction was useful in molecular biology and that primers to amplify exon regions were also useful. This is shown by Vijg et al., who disclose a method for PCR primer identification using parameters such as melting temperature. Vijg et al. specifically state that primers for the amplification of multiple exons from a gene can be identified, designed, and collated by the disclosed system (page 5, line 22).

It would have been *prima facie* obvious to one of skill in the art at the time the invention was made to use the method of Shannon et al. to find specific, selective primers that would amplify regions of interest in conjunction with the method of Vijg et al. for exon identification/prediction.

Neither Shannon et al. nor Vijg et al. teach that parallel simultaneous processing is used in their systems. However, Balch does teach a method for analyzing molecular structures within a sample substance. As described, it is desirable to rapidly detect and quantify one or more molecular structures in a sample. In particular, the invention provides a multiplexed environment to rapidly determine optimal assay parameters, as well as fast, cost effective, and

accurate systems for the quantitative analysis of target analytes, thereby circumventing the limitations of single determination assays (Column 4, lines 1-9). Furthermore, the array system described is capable of parallel processing a large number of samples. Large clinical labs could use this, for example, to perform simultaneous tests on thousands of samples (column 4, lines 39-47). Another use would be for the creation of hierarchical assays for complex analyses.

Multiple arrays operate in parallel such that for any specific analysis a set of probe elements must be chosen. The selected probe elements should be able to selectively associate with defined targets without significant cross association to other macromolecules column 5, lines 1-16).

While Blach does not specifically speak of primers for predicted exons, it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to automate the systems of Shannon and Vijg such that the primers could be developed in parallel and simultaneously, as is done in the molecular structure analysis method of Blach.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am-6:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 14, 2003

Lori A. Clow, Ph.D.
Art Unit 1631

Lori A. Clow

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